

REMARKS

Claims 1 to 7 and 9 to 12 remain in prosecution with claim 8 cancelled.

1. The Examiner rejected claims 1 to 4, 6-10-12 under 35 U.S.C. 103 as being obvious over Bower et al. US Patent, 6,086,558 in view of Crowley, US 6,354,831 for the reasons noted on Pages 2-3; and rejected claim 5 under 35 U.S.C. 103 in further view of Berry, US 6,254,594.

Bower et al. deals with producing and using special diffuser tips for optical fibers. The reflective coating described in the column 6 reference are there to restrict the exit of the light transmitted from a proximally sourced radiation source to the distal end. Along the length of the diffuser the scattered light is diminished at the ends of the diffuser, so the invention removes this light or blocks some sector of the central section of the balloon to project radiation through only a sector of the balloon thus 'protecting' the tissue opposite such blocked sector.

In contrast the present invention requires no balloon or other means to artificially block off sectors to homogenize light on a treatment site. As an active endoscope, the controls at the proximal end can direct the energizing of various light sources at the distal, placed directly there, so that the irradiation of the desired tissue is accomplished in the pattern most efficient for the treatment area/site. Balloons used in the examples deal primarily with the prior art standard uses to open up a channel in a body cavity; to help provide a fixed distance generally from the fiber tip within the balloon.

A unique exception is the use of a double walled balloon with a chemiluminescent liquid circulated between the walls and whose output is used, in a novel fashion, to provide the energy to activate photosensitizers in the tissue needing treatment. This is why the use of a chemiluminescent source is not obvious from the prior art nor would have been expected to be easy to accomplish. Here we have a truly distributed radiation source providing homogeneous, scattered radiation to activate photosensitizers to achieve PhotoDynamic Therapy (PDT).

As to Crowley, first of all those skilled in the art would not routinely look at reports, patents or other writings on diagnostic methods to achieve surgical results. Even for PDT, which uses lower light levels than for radiation-induced surgery, practitioners normally look to individual sources as e.g. the examiner's reference, Chen et al. US 5,800,478. The main point being expect for someone doing 'blind' keyword searches using words provided by an inventor, there is no

reason to search diagnostic patents such as Crowley's fluorescence method/device to consider such in combination with either Bower et al. or Chen.

Secondly, Crowley is presenting a small add on, which is removable, for endoscopes to provide for tissue spectroscopy with a source, encapsulated at the distal end. Conceptually one might think it was similar to attaching a diffuser tip to a fiber's distal end, but again the present invention is not a mere add on in the distal area. The present invention as claimed provides a number of sources or a distributed radiation source to provide homogenized, scattered radiation to tissue carrying a photosensitizer to achieve PDT. In one embodiment it covers a major portion of the exterior of the specialized catheter with the radiation sources, and in the chemiluminescent embodiment the entire volume between the double-walled balloon is used to bring the chemiluminescent fluid into the cavity to be treated with PDT. Neither of these approaches are similar to the cases described in any of the prior art references.

In this context also the Berry patent deals with an approach which is a modified, specialized sort of chemiluminescence, in that as noted (Abstract) the system "utilizes a disposable sample cell that contains a chemical mixture capable of photoinitiation. Upon photoinitiation a chemical reaction creates electromagnetic radiation that is readily absorbed....". Berry describes a system that needs to be photo initiated to create the chemiluminescence. There is no such requirement in the present invention. In fact, as described therein, chemicals can simply be mixed to initiate the luminescence and the fluid mixture flowed through the double-walled balloon to maintain a fresh active, homogeneous radiation over the desired treatment time. Thus Berry really does address the type of chemiluminescence of the present invention nor provides any teaching on how it could be done within the confines of the distal end of a catheter.

Thus first claim 1 as now modified is not made obvious by any of the combinations of prior art brought forth by the examiner, (Bower et al. & Crowley, or Chen et al.) nor does the added combination with Berry make obvious the specifics of claim 5. Lastly the provision in claim 7 of a contiguous means to deliver the PDT active material with the catheter system in place is equally unique, not anticipated nor made obvious by Chen et al. or any combination with Bower et al. or Crowley.

In the prior reply, applicants raised all the arguments about the lack of teachings by Chen et al. as to the claimed specifics of claims 1-7, 9-12. These are include here by reference.

With these remarks it is believed that the requirements of 35 USC, 37 CFR and the MPEP have been answered and the disclosure and claims are now in condition for examination as one whole invention. Consideration is respectfully requested. An early and favorable response is earnestly solicited. Thank you.

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Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Bolesh J. Skutnik', written in a cursive style.

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